UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GEMINI INSURANCE COMPANY,

Plaintiff,

v.

CASE NO.: 18-CV-4378 (RJS)

ACELLA PHARMACEUTICALS, LLC, HAROLD ARTHUR DEAS, THOMAS JEFFREY BRYANT, NEIL ACKERMAN AND SHEILA AKERMAN,

ANSWER ON BEHALF OF NEIL AKERMAN and SHEILA AKERMAN

Defendants.

Defendants, Neil Akerman and Sheila Akerman (hereinafter the "Akermans"), by and through their attorneys, Gleason, Dunn, Walsh & O'Shea, as and for an Answer to the Complaint of Plaintiff, Gemini Insurance Company respectfully submit as follows:

1. Admit the allegations in Paragraphs 3, 5, 14, 16, 19, 20, 21, 22, 23, 26, 36, 38, 41, 43, 49 and 53 of the Plaintiff's Complaint.

2. Deny knowledge or information sufficient to form a belief, and therefore denies each and every allegation contained in Paragraphs 4, 6, 7, 8, 9, 10, 28, 29, 30, 31, 32, 33, 34, and 47 of Plaintiff's Complaint.

3. Deny each and every allegation contained in Paragraphs 39, 44, 50, and 54 of Plaintiffs Complaint.

4. Deny each and every allegation contained in Paragraph 1 of Plaintiff's Complaint, except admit that after a bench trial Judge Richard A. Sullivan ("Judge Sullivan") issued a written opinion in *Merck Eprova AG. v Brookstone Pharmaceuticals LLC., et al.* 920 F. Supp. 2d 404 (S.D.N.Y., 2013) (*Merck* decision), which opinion contained Findings of Fact and

Conclusions of Law which such Findings of Fact and Conclusions of Law are set forth in Judge Sullivan's opinion and, speak for themselves—and determined, among other things that the conduct of Acella Pharmaceuticals, LLC ("Acella"), Harold Arthur Deas ("Deas") and Thomas Jeffrey Bryant ("Bryant") violated the Lanham Act.

5. Deny each and every allegation contained in Paragraph 2 of Plaintiff's Complaint, except admit that among other things, Acella, among other parties, was sued by the Akermans, individually and as parents and natural guardians of their infant daughter Emma Akerman because, *inter alia*: (a) Acella's product, Neurpath-B and its underlying source of folates, Xolafin-B, were defective; (b) Acella was negligent and grossly negligent in formulating, manufacturing, labeling, promoting, advertising and selling Neurpath-B and its underlying source of folates, Xolafin-B; (c) Acella breached its warranties; and (d) Acella falsely and misleadingly labeled and promoted Neurpath-B and its underlying source of folates, Xolafin-B, all of which conduct resulted in Emma Akerman being born with a neural tube defect, spina bifida, that has left her paralyzed, among other injures; and that significant portions of Acella's conduct involved the same tortious conduct as was judicially determined by Findings of Fact and Conclusions of Law in the *Merck decision.*

6. Deny each and every allegation contained in Paragraph 11 of Plaintiff's Complaint, except admit that the Akermans are residents of the State of New York, and that they each individually and as parents and natural guardians of their infant daughter Emma Akerman have sued Acella, among other parties, for damages, as result of the improper and unlawful substitution of Acella's Neurpath-B for Metanx, which had been prescribed for Sheila Akerman, and that the lawsuit alleges against Acella, *inter alia*, that: (a) Acella's product, Neurpath-B and its underlying source of folates, Xolafin-B, were defective; (b) Acella was negligent and grossly

negligent in formulating, manufacturing, labeling, promoting, advertising and selling Neurpath-B and its underlying source of folates, Xolafin-B; (c) Acella breached its warranties; and (d) Acella falsely and misleadingly labeled and promoted Neurpath-B and its underlying source of folates, Xolafin-B, all of which conduct resulted in Emma Akerman being born with a neural tube defect, spina bifida, that has left her paralyzed, among other injuries.

7. Deny knowledge or information to form a belief and therefore must deny each and every allegation contained in Paragraphs 12 and 13 of Plaintiff's Complaint, except admit that Merck Eprova AG, ("Merck") sued Brookstone Pharmaceuticals, a/k/a Acella, Deas and Bryant in the United States District Court for the Southern District of New York for their conduct arising out of the manufacture, sale, labeling and promotion of Acella's products which contained Xolafin and Xolafin-B as a source of "folates," the allegations in such action speaking for themselves.

8. Deny each and every allegation contained in Paragraph 15 of Plaintiff's Complaint, except admit that Judge Sullivan made Findings of Fact and Conclusions of Law, which such Findings of Fact and Conclusions of Law are set forth in his opinion, and speak for themselves, and include, among other things, findings that Acella, Bryant and Deas violated the Lanham Act.

9. Deny each and every allegation contained in Paragraph 17 of Plaintiff's Complaint, except admit that Judge Sullivan made Findings of Fact and Conclusions of Law, which such Findings of Fact and Conclusions of Law are set forth in his opinion, and speak for themselves, and include, among other things, a finding of treble damages owed by Acella to Merck.

10. Deny each and every allegation contained in Paragraph 18 of Plaintiff's Complaint, except admit that Judge Sullivan made Findings of Fact and Conclusions of Law, which such

Findings of Fact and Conclusions of Law are set forth in his opinion, and speak for themselves, and include, among other things, a finding that Acella owed attorneys' fees to Merck.

11. Deny each and every allegation contained in Paragraphs 24, 37, 42 and 48 of Plaintiff's Complaint, except admit that the Acella product at issue in the "*Akerman* litigation" described herein, Neurpath-B, contained the Acella product Xolafin-B as its source of "folates" both of which were products and substances at issue in the *Merck* litigation, and which were the subjects of Judge Sullivan's Findings of Fact and Conclusions of Law in that litigation, and that many, if not all of the facts and circumstances relating to the tortious conduct of Acella, Deas and Bryant that give rise to the injuries set forth in the *Akerman* litigation are identical to the facts and circumstances in the Merck litigation.

12. Deny each and every allegation contained in Paragraph 25 of Plaintiff's Complaint, except admit that Emma Akerman was born with spina bifida, leaving her paralyzed among other injuries, which injuries resulted from the negligent, improper and unlawful substitution by CVS Albany, LLC ("CVS") of Neurpath-B for Metanx—which had been prescribed for Sheila Akerman for the express purpose of preventing spina bifida—and from the fact, among other things, that: (a) Acella's product, Neurpath-B and its underlying source of folates, Xolafin-B, was defective; (b) Acella was negligent and grossly negligent in formulating, manufacturing, labeling, promoting, advertising and selling Neurpath-B and its underlying source of folates, Xolafin-B; (c) Acella breached its warranties; and (d) Acella falsely and misleadingly labeled Neurpath-B and its underlying source of folates, Xolafin-B.

13. Deny each and every allegation contained in Paragraph 27 of Plaintiff's Complaint, except admit that in the *Akerman* litigation against CVS and Acella it is alleged that, under both the common law and statutes of the State of New York, the tortious conduct of Acella, Deas,

Bryant and CVS meets the standard to determine that in addition to compensatory damages, each of the defendants are liable to the plaintiffs for exemplary and/or punitive damages.

14. Deny each and every allegation contained in Paragraphs 46 and 52 of Plaintiff's Complaint, except admit that Judge Sullivan made Findings of Fact and Conclusions of Law, which such Findings of Fact and Conclusions of Law are set forth in his opinion, and speak for themselves, and include, among other things findings that Acella, Bryant and Deas intentionally mislabeled Acella's folate products and intentionally marketed its Xolafin and Xolafin-B products, including Neurpath-B, to create the impression that they were identical to pure folate containing products, including Metanx; and that Acella intentionally induced pharmaceutical databases to improperly link its products to pure folate products with which it sought to compete, and tracked "competing" folate products to avoid having Acella's folate products delinked.

15. To the extent that the Paragraphs 35, 40, 45, and 51 of Plaintiff's Complaint, incorporate the allegations of Paragraphs 1 through 34 of Plaintiff's Complaint, the Akermans, repeat, reiterate and reallege each and every admission and denial as set forth herein applicable to each such allegation.

16. The Akermans deny each and every allegation in Plaintiff's Complaint not specifically and expressly admitted or otherwise responded to herein.

AS AND FOR A FIRST AFFIRMATIVE DEFENSE

16. Plaintiff's claims fail to state a cause of action upon which relief may be granted.

AS AND FOR A SECOND AFFIRMATIVE DEFENSE

17. Plaintiff's claims are barred under the doctrine of laches, including as a result of Plaintiff's failure to timely disclaim liability and/or deny coverage.

AS AND FOR A THIRD AFFIRMATIVE DEFENSE

18. Plaintiff's claims have been waived, including as a result of Plaintiff's failure to timely disclaim liability and/or deny coverage.

AS AND FOR A FOURTH AFFIRMATIVE DEFENSE

19. Plaintiff is estopped from asserting its claims, including as a result of Plaintiff's failure to timely disclaim liability and/or deny coverage.

AS AND FOR A FIFTH AFFIRMATIVE DEFENSE

20. Plaintiff's claims fail to state a cause of action upon which relief can be granted because Plaintiff's purported bases for disclaimer rely on disputed issues in the *Akerman* litigation.

AS AND FOR A SIXTH AFFIRMATIVE DEFENSE

21. Plaintiff's claims are barred as a result of Plaintiff's failure to comply with Plaintiff's obligations under the New York State statutes and common law, including, but not limited to, Section 3420 of the New York State Insurance Law.

AS AND FOR A SEVENTH AFFIRMATIVE DEFENSE

22. Plaintiff's claims are barred because, at a minimum, some of the allegations and theories in the Akerman litigation are covered.

WHEREFORE, the Akermans respectfully request Judgment:

a. Declaring that the Findings of Fact and Conclusions of Law of Judge Sullivan in his Decision of January 30, 2013 in the *Merck* litigation are binding on Acella, Deas and Bryant in the *Akerman* litigation.

b. Declaring that that the Gemini policy provides coverage to pay any judgment for compensatory damages against Acella, Deas, and/or Bryant from the *Akerman* litigation.

c. Such other and further relief as the Court may deem just and proper.

Dated: July 3, 2018
Albany, New York

Yours, etc.

GLEASON, DUNN, WALSH & O'SHEA

By: _____

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